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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,253	07/15/2003	Rosanne Crooke	ISPH-0590US.P1	9025

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MARY E. BAK
HOWSON AND HOWSON, SPRING HOUSE CORPORATE CENTER
BOX 457
SPRING HOUSE, PA 19477

EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,253	CROOKE ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3-23, drawn to oligonucleotides that hybridize to a nucleic acid encoding human stearoyl-CoA desaturase identified as nucleotides 1-69 of SEQ ID NO: 3, classifiable in class 536, subclass 24.5. Election of this group requires a further election of a single antisense sequence from claim 13 for the reason explained below.

II. Claims 3-23, drawn to oligonucleotides that hybridize to a nucleic acid encoding human stearoyl-CoA desaturase identified as nucleotides 92-241 of SEQ ID NO: 3, classifiable in class 536, subclass 24.5. Election of this group requires a further election of a single antisense sequence from claim 13 for the reason explained below.

III. Claims 3-23, drawn to oligonucleotides that hybridize to a nucleic acid encoding human stearoyl-CoA desaturase identified as nucleotides 263-859 of SEQ ID NO: 3, classifiable in class 536, subclass 24.5. Election of this group requires a further election of a single antisense sequence from claim 13 for the reason explained below.

IV. Claims 3-23, drawn to oligonucleotides that hybridize to a nucleic acid encoding human stearoyl-CoA desaturase identified as nucleotides 883-5221 of SEQ ID NO: 3, classifiable in class 536, subclass 24.5. Election

of this group requires a further election of a single antisense sequence from claim 13 for the reason explained below.

V. Claims 24-29, 31 and 32, drawn to a method of inhibiting expression of human stearoyl-CoA desaturase with an antisense oligonucleotide in cells or tissue, classifiable in class 514, subclass 44.

VI. Claim 30, drawn to a method of screening for a modulator of human stearoyl-CoA desaturase, classifiable in class 435, subclass 6.

VII. Claim 33, drawn to duplex oligonucleotides targeted to human stearoyl-CoA desaturase, classifiable in class 536, subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention I is to hybridize with nucleotides 1-69 of SEQ ID NO: 3, the function of invention II is to hybridize with nucleotides 92-241 of SEQ ID NO: 3, the function of invention III is to hybridize with nucleotides 263-859 of SEQ ID NO: 3 and the function of invention IV is to hybridize with nucleotides 883-5221 of SEQ ID NO: 3.

2. Furthermore, searching any of inventions I-IV together would impose a serious search burden. In the instant case, prior art searches of oligonucleotides that hybridize with one portion of a nucleic acid encoding human stearoyl-CoA desaturase are not

coextensive with prior art searches of oligonucleotides that hybridize with a different portion of a nucleic acid encoding human stearoyl-CoA desaturase. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. Searches of largely different regions of a sequence in computerized databases would require subsequent in-depth analysis of the results and how the results relate to the different regions of the sequence claimed, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-IV together.

3. Claims 1 and 2 link(s) inventions I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 2. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Inventions I-IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product could be used in a materially different process, for example in *in vitro* hybridization assays.

5. Furthermore, searching inventions I-IV together with invention V would impose a serious search burden. In the instant case, prior art searches of oligonucleotides that hybridize with human stearoyl-CoA desaturase are not coextensive with prior art searches of methods of inhibiting expression of human stearoyl-CoA desaturase in cells. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-IV and V together.

6. Inventions I-IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-IV is to hybridize with human stearoyl-CoA desaturase while the function of invention VI is to screen for modulators of human stearoyl-CoA desaturase.

7. Furthermore, searching inventions I-IV together with invention VI would impose a serious search burden. In the instant case, prior art searches of oligonucleotides that hybridize with human stearoyl-CoA desaturase are not coextensive with prior art searches of methods of screening for compounds that modulate human stearoyl-CoA desaturase. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-IV and VI together.

8. Inventions I-IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Inventions I-IV hybridize with human stearoyl-CoA desaturase and inhibit gene expression by RNAse H cleavage while invention VII inhibits gene expression in concert with the RISC complex.

9. Furthermore, searching inventions I-IV together with invention VII would impose a serious search burden. In the instant case, prior art searches of oligonucleotides that hybridize with human stearoyl-CoA desaturase and activate RNAse H are not coextensive with prior art searches of double stranded oligonucleotides targeted to human stearoyl-CoA desaturase that inhibit gene expression in concert with the RISC

complex. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-IV and VII together.

10. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention V is to inhibit expression of human stearoyl-CoA desaturase while the function of invention VI is to screen for modulators of human stearoyl-CoA desaturase.

11. Furthermore, searching invention V together with invention VI would impose a serious search burden. In the instant case, prior art searches of methods of inhibiting expression of human stearoyl-CoA desaturase are not coextensive with prior art searches of methods of screening for compounds that modulate human stearoyl-CoA desaturase. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions V and VI together.

12. Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention V is to inhibit expression of human stearoyl-CoA desaturase with an antisense oligonucleotide while invention VII is a duplex that inhibits gene expression in concert with the RISC complex.

13. Furthermore, searching invention V together with invention VII would impose a serious search burden. In the instant case, prior art searches of methods of inhibiting expression of human stearoyl-CoA desaturase with an antisense oligonucleotide are not coextensive with prior art searches of duplexes that inhibit human stearoyl-CoA desaturase through the RISC complex. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions V and VII together.

14. Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of

invention VI is to screen for modulators of human stearoyl-CoA desaturase while invention VII is a duplex that inhibits gene expression in concert with the RISC complex.

15. Furthermore, searching invention VI together with invention VII would impose a serious search burden. In the instant case, prior art searches of methods of screening for modulators of human stearoyl-CoA desaturase are not coextensive with prior art searches of duplexes that inhibit human stearoyl-CoA desaturase through the RISC complex. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions VI and VII together.

Restriction to a single nucleotide sequence

Claim 13 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not

require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1)share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 13 specifically claims multiple human stearoyl-CoA desaturase antisense SEQ ID NOS, which are targeted to and modulate the expression of human stearoyl-CoA desaturase. Although the antisense sequences claimed each target and modulate expression of human stearoyl-CoA desaturase, the instant antisense sequences are considered to be unrelated, since each antisense sequence claimed is structurally and functionally independent and distinct for the following reasons: each antisense sequence has a unique nucleotide sequence, each antisense sequence targets a different and specific region of a human stearoyl-CoA desaturase nucleic acid, and each antisense, upon binding to a human stearoyl-CoA desaturase nucleic acid, functionally modulates (increases or decreases) the expression of the gene and to varying degree (per applicants' Table 1 in the specification). As such the Markush/genus of sequences in claim 13 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the sequences claimed in claim 13 presents an undue burden on the Patent and Trademark Office due to the

complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. In view of the foregoing, one (1) nucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) sequence from claim 13. Note that this is not a species election.

16. Claim 1 link(s) the inventions of claim 13. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

17. If any of groups I-IV is elected, applicant must further elect a single antisense sequence from claim 13.

18. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

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Tracy Vivlemore
Examiner
Art Unit 1635

TV
May 13, 2005

JAMES SCHULTZ
PATENT EXAMINER